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Docket No. GJE-68
Serial No. 09/856,944In the Claim

1 (currently amended). An endogenous material, inducible in a mammal by clomiphene,
having the ability to reduce the mass of body organs (including non-gonadal organs) the material
being obtained by:

collecting ovarian venous blood from a female mammal;

preparing ovarian venous plasma from the blood; and

at least partially purifying said material from the plasma to obtain at least a nominal 10-30 kD
sub-fraction.

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2 (cancel).

3 (currently amended). The material according to claim 1, wherein the purifying comprises
obtaining ~~the~~ a 10-20 kD fraction.

C1
4 (previously amended). The material according to claim 3, wherein the purifying
additionally comprises ion exchange chromatography, and collecting the fraction eluted in 0.1-0.2 M
NaCl.

5 (currently amended). The material according to claim 1, wherein the purifying comprises
the following protocol:

clearing plasma by centrifugation;

spinning the cleared plasma to give a nominal 0-30 kD fraction;

spinning the nominal 0-30 kD fraction to give [a]the nominal 10-30 kD sub-fraction;

concentrating and gel-filtering the nominal 10-30 kD sub-fraction to give a nominal 10-20
kD sub-fraction;

concentrating and buffer-diluting the nominal 10-20 kD sub-fraction repeatedly;

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applying the concentrate and buffer-diluted nominal 10-20 kD sub-fraction repeatedly to an ion exchange column eluted with a gradient of 0-.3 M NaCl; and
dividing the eluate into 0-0.1 M, 0.1-0.2 M and 0.2-0.3 M NaCl ion exchange fractions.

6 (previously amended). The material according to claim 1, wherein the mammal is a sheep.

7 (previously canceled).

8 (currently amended). A pharmaceutical composition comprising an endogenous material inducible by clomiphene, having the ability to reduce the mass of body organs including non-gonadal organs, the material being obtained by:

collecting ovarian venous blood from a female mammal;

preparing ovarian venous plasma from the blood; and

C1 at least partially purifying said material from the plasma to obtain at least a nominal 10-30 kD sub-fraction

and a pharmaceutically acceptable excipient or carrier.

9 (previously canceled).

10 (cancel).

11 (previously added). The pharmaceutical composition, according to claim 8, wherein the purifying comprises obtaining the 10-20 kD fraction.

12 (previously added). The pharmaceutical composition, according to claim 8, wherein the purifying additionally comprises ion exchange chromatography, and collecting the fraction eluted in 0.1-0.2 M NaCl.

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13 (currently amended). The pharmaceutical composition, according to claim 8, wherein the purifying comprises the following protocol:

- clearing plasma by centrifugation;
- spinning the cleared plasma to give a nominal 0-30 kD fraction;
- spinning the nominal 0-30 kD fraction to give [a] the nominal 10-30 kD sub-fraction;
- concentrating and gel-filtering the nominal 10-30 kD sub-fraction to give a nominal 10-20 kD sub-fraction;
- concentrating and buffer-diluting nominal 10-20 kD sub-fraction repeatedly;
- applying the concentrated and buffer-diluted nomi[c]nal 10-20 kD sub-fraction repeatedly to an ion exchange column eluted with a gradient of 0-.3 M NaCl; and
- dividing the eluate into 0-0.1 M, 0.1-0.2 M and 0.2-0.3 M NaCl ion exchange fractions.

C1 14 (previously added). The pharmaceutical composition, according to claim 8, wherein the mammal is a sheep.

15 (currently amended). A method for treating organ or tissue hypertrophy wherein said method comprises administering, to a patient in need of such treatment, an effective amount of an endogenous material, inducible by clomiphene, having the ability to reduce the mass of body organs including non-gonadal organs, the material being obtained by:

- collecting ovarian venous blood from a female mammal;
- preparing ovarian venous plasma from the blood; and
- at least partially purifying said material from the plasma to obtain at least a nominal 10-30 kD sub-fraction.

16 (cancel).

17 (previously added). The method, according to claim 15, wherein the purifying comprises obtaining the 10-20 kD fraction.

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18 (previously added). The method, according to claim 15, wherein the purifying additionally comprises ion exchange chromatography, and collecting the fraction eluted in 0.1-0.2 M NaCl.

19 (previously amended). The method, according to claim 15, wherein the purifying comprises the following protocol:

clearing plasma by centrifugation;

spinning the cleared plasma to give a nominal 0-30 kD fraction;

spinning the nominal 0-30 kD fraction to give [a]the nominal 10-30 kD sub-fraction;

concentrating and gel-filtering the nominal 10-30 kD sub-fraction to give a nominal 10-20 kD sub-fraction;

concentrating and buffer-diluting the nominal 10-20 kD sub-fraction repeatedly;

C1 applying the concentrated and buffer-diluted nominal 10-20 kD sub-fraction repeatedly to an ion exchange column eluted with a gradient of 0-.3 M NaCl; and

dividing the eluate into 0-0.1 M, 0.1-0.2 M and 0.2-0.3 M NaCl ion exchange fractions.

20 (previously amended). The method, according to claim 15, wherein the mammal from which the ovarian venous blood is collected is a sheep.

21 (new). The method, according to claim 15, wherein the patient is in need of treatment for the group consisting of prostatic hypertrophy, cardiac hypertrophy, polycystic ovarian syndrome, endometriosis, polycystic renal disease, and pituitary adenoma.
